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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/291,894	04/13/1999	PETER L. COLLINS	17634-000520	2725

20350 7590 02/12/2003

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EXAMINER	
LUCAS, ZACHARIAH	
ART UNIT	**PAPER NUMBER**
1648	26

DATE MAILED: 02/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/291,894	COLLINS ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35 and 46-65* is/are pending in the application.

4a) Of the above claim(s) *13-15,17,22-34 and 60-63* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,16,18,35,46-59,64 and 65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Claims

1. Claims 1-35 and 46-65 are currently pending in the application. Claims

2. The Art Unit location of your application, and the examiner to whom the case has been docketed in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Zachariah Lucas in Art Unit 1648.

Specification

3. **(New Objection- Necessitated by Amendment)** The amendment filed on November 25, 2002 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the incorporation by reference of the subject matter disclosed in priority documents 08/720,132 (now U.S. Patent 6,264,957) and 60/007,083. While the applicant is permitted to claim priority to these documents for subject matter already disclosed in the present case, the applicant is not permitted to incorporate the entirety of these applications by reference as doing so introduces material that was not previously in the application into the present application. Applicant is required to cancel the new matter (the incorporation by reference) in the reply to this Office Action.

Double Patenting

4. **(Prior Rejection-Maintained)** Claims 1-12, 16, 18-21, 35, 46-59, and 64-65 are rejected for the reasons of record under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 96-103, 131, 151-153 of copending Application No. 09/444,067, and claims 20,31,and 56 of copending application 09/444,221.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. **(New Rejection)** Claims 1-35, and 43-65 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims read on embodiments of the claimed chimeric RSV wherein the virus comprises a RNA polymerase elongation protein. Thus, the claim as written encompasses a generic class of chimeric RSV virus, each of which may contain any RNA polymerase elongation factor. The specification does not provide adequate written description support for the full scope of these generic claims.

The following quotation from section 2163 of the Manual of Patent Examination Procedure is a brief discussion of what is required in a specification to satisfy the 35 U.S.C. 112 written description requirement for a generic claim covering several distinct inventions:

> The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice..., reduction to drawings..., or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus... See Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406.
>
> A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

Also relevant to the discussion are the following excerpts from the case of In re Borkowski and Van Venrooy, 164 USPQ 642, (CCPA 1970). In describing the appropriate grounds for a claim rejection when the claim exceeds the scope of the disclosure, the court stated the following:

> *...a specification need not contain a working example if the invention is otherwise disclosed in such a manner that one skilled in the art will be able to practice it without an undue amount of experimentation.* (Excerpt from164 U.S.P.Q. at 645)

and;

> *... if the "enabling" disclosure of a specification is not commensurate in scope with the subject matter encompassed by a claim, that fact does not render the claim imprecise or indefinite or otherwise not in compliance with the second paragraph of §112; rather, the claim is based on an insufficient disclosure 4 (§112, first paragraph) and should be rejected on that ground. See In re Fuetterer, 50 CCPA 1453, 319 F.2d 259, 138 USPQ 217 (1963); In re Kamal, 55 CCPA 1409, 398 F.2d 867, 158 USPQ 320 (1968); and In re Wakefield, 164 USPQ (PA 8192), decided concurrently herewith. Thus, just as a claim which is of such breadth that it reads on subject matter disclosed in the prior art is rejected under §102 rather than under the second paragraph of §112, a claim which is of such breadth that it reads on subject matter as to which the specification is not "enabling" should be rejected under the first paragraph of §112.* (Excerpt from 164 U.S.P.Q. at 646).

Thus, when a claim covers a genus of inventions the specification must provide written description support for the entire scope of the genus. Support for a genus is generally found where the applicant has provided a number of examples sufficient so that one in the art would

recognize from the specification the scope of what is being claimed. However, a disclosure will also support the claims in the absence of examples if the description would enable one in the art to practice the invention without such guidance.

In the present case, the applicant has disclosed only a single example of a RNA polymerase elongation factor- the M2 ORF 1 protein of RSV. See e.g., pages 14, lines 6-9; and page 64, lines 3-7. Although the specification states that a "substantially equivalent transcription elongation factor" may be used instead of the M2 ORF1, neither the description nor the examples in the application provide any indication of what such substantially equivalent factors may be. Without examples, or some identification of the M2 ORF1 structure that is necessary to its operation, one in the art wishing to practice the invention has no indication as to what other proteins may be used in the claimed virus. In view of the lack of description for any RNA polymerase elongation factor other than the M2 ORF1, the claims are rejected for exceeding the scope of descriptive support provided by the specification.

7. **(New Rejection)** Claims 1-35, and 46-65 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated infectious chimeric RSV wherein the virus comprises the M2 (ORF1) RNA polymerase elongation factor, does not reasonably provide enablement for viruses containing any RNA polymerase elongation factor. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

A claim is commensurate in scope with the enablement when the applicant has provided sufficient disclosure to enable one skilled in the art to practice the claimed invention without

undue experimentation. In re Wands, 8 USPQ2d 1400, 1404 (CAFC 1988). There must be a "reasonable correlation" between the scope of enablement and the scope of the claims. In re Fisher, 166 U.S.P.Q. 18, 24 (CCPA 1970). Such correlation requires "sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and how to use the invention as broadly as it is claimed. This means that the disclosure must adequately guide the art worker to determine, without undue experimentation, which species among all those encompassed by the claimed genus possess the disclosed utility." See, In re Vaeck, 20 U.S.P.Q.2d 1438, 1444 (CAFC 1991) No such guidance is provided in the present case.

Both the present application (page 64, lines 3-20), and the art relevant to the claimed invention (see, Collins et al. PNAS 92:11563-11567- made of record in the IDS filed February 1, 2000), indicates that the M2 ORF1 protein is one of the minimal proteins necessary for an infectious RSV. Although the application does state that substantial equivalents of this identified protein may be used (page 63, lines 35-38), it does not identify any characteristic or examples which one of ordinary skill in the art could use as guides to identify such equivalents. Further, the combined teachings of the specification, indicating that only substantial equivalents of the M2 ORF1 protein may be used, and the art, teaching that an operative M2 ORF1 protein is necessary for an operative chimeric RSV (Collins et al., PNAS 92:11563-11567), indicate that only a specific subclass of RNA polymerase elongation factors may be used in the invention. As the application has provides no examples or other indication as to what proteins fall within this subclass, other than the M2 ORF1 protein itself, the application has not provided an enabling disclosure corresponding to the full scope of the rejected claims.

Claim Rejections - 35 USC § 103

8. **(Prior Rejection- Withdrawn)** Claims 1-12, 16, 18-21, 35, 46-59, 64, and 65 were rejected in the prior action under 35 U.S.C. 103(a) as being unpatentable over Murphy et al. in view of Collins et al. In view of the newly added claim to priority to application 08/720,132, now patent 6,264,957, which claims benefit to provisional application 60/007,083, which predates the Collins reference, and teaches the subject matter disclosed therein, the rejection is hereby withdrawn.

Conclusion

9. The following prior art references are made of record and are considered pertinent to applicant's disclosure. However, while relevant they are also not used as a basis for rejection for the stated reasons.

U.S. Patent 5,840,520, issued to Clarke et al. This patent teaches chimeric recombinant RSV that contain heterologous DNA coding sequences. However, the reference teaches neither that the heterologous sequence encodes a G protein from a different RSV virus, or the inclusion of the M2 ORF1 protein in the recombinant viral particle.

U.S. Patent 5,716,821, issued to Wertz et al., made of record in the IDS filed on February 1, 2000. This reference also teaches recombinant RSV containing a heterologous DNA coding sequence. This reference does not teach that the M2 ORF1 protein is necessary to the infectious virus.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 703-308-4240. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Z. Lucas
Patent Examiner
January 30, 2003

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